Press Release

For media and investors only

Issued: 30 March 2023, London UK

Medicines Patent Pool signs sublicences with Aurobindo, Cipla and Viatris to produce generic versions of ViiV Healthcare's innovative long-acting HIV prevention medicine

- ***Licences should enable potentially millions of people living in areas most impacted by HIV to access this innovative prevention medicine through low-cost generic manufacturers***
- ***Announcement includes potential for large scale manufacturing on the continent of Africa***

London, 30 March 2023 – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, together with the Medicines Patent Pool (MPP) have today announced that MPP has signed sublicence agreements with Aurobindo, Cipla and Viatris – through its subsidiary Mylan – to manufacture generic versions of cabotegravir long-acting (LA) for HIV pre-exposure prophylaxis (PrEP). This is enabled by the signing of a voluntary licensing agreement for patents relating to cabotegravir LA for PrEP with MPP in July 2022.

According to UNAIDS' latest estimates, approximately 1.5 million people acquired HIV worldwide in 2021, among whom 860,000 live in sub-Saharan Africa, with women and adolescent girls disproportionately impacted.[1,2] While oral PrEP options are now available in many countries, access to cabotegravir LA for PrEP could significantly contribute to reducing HIV transmission by providing people a choice in their HIV prevention options.

Only seven months after the first regulatory approval of cabotegravir LA for PrEP in the world by the US Food and Drug Administration (FDA),[3] ViiV Healthcare and MPP signed a voluntary licence agreement in July 2022 for patents relating to cabotegravir LA for PrEP to help enable access in all least developed, low-income, lower-middle-income and sub-Saharan African countries.[4,5] This licence builds on a long-standing partnership between ViiV Healthcare and MPP, which has been highly successful in facilitating the manufacture and sale of generic versions of oral ViiV Healthcare medicines in countries most affected by HIV and least able to pay for treatment and care.

Deborah Waterhouse, CEO at ViiV Healthcare, said: "Cabotegravir LA for PrEP has the potential to change the trajectory of HIV. The signing of sublicence agreements with three generic partners is an incredibly important milestone towards enabling broad access to this medicine in countries where there is the highest burden of new HIV cases. We are committed to working together with MPP and the selected generic manufacturers at pace to help enable development, manufacturing, and supply."

Press Release

For media and investors only

Through the MPP-ViiV Healthcare agreement, the selected generic manufacturers will be able to develop, manufacture, and supply generic versions of cabotegravir LA for PrEP, in 90 countries, subject to required regulatory approvals being obtained. Aurobindo and Viatris will manufacture in India; Cipla will manufacture in India and has plans to manufacture in South Africa as well. These three manufacturers were selected through an open call for Expressions of Interest, which included a blinded assessment of applications and an on-site technical assessment of short-listed applicants to enable selection of manufacturers with proven technical expertise, capacity, and readiness (in terms of specialist manufacturing equipment) to develop long-acting nano-suspension based injectable formulations.

Compared to oral HIV prevention options, cabotegravir LA for PrEP is more complex to manufacture and ViiV Healthcare is committed to supporting Aurobindo, Cipla and Viatris with technical know-how to enable development and access as soon as possible.

Charles Gore, Executive Director of MPP, said: "These three sublicence agreements are the first that MPP has signed for a long-acting medicine, and we are thrilled to be moving concretely into this space as these generic versions of cabotegravir LA for PrEP will contribute to broadening access to innovative long-acting prevention medicines in low- and middle-income countries. MPP is ready to support the selected generic manufacturers who can also count on our long-standing partner ViiV Healthcare to support the development process."

MPP, the selected manufacturers and ViiV Healthcare, will continue to work with the Coalition to Accelerate Access to Long-Acting PrEP – convened by the Global Fund, PEPFAR, UNAIDS, Unitaid, and the World Health Organization (WHO) with AVAC as the Secretariat – to find tangible, practical solutions to accelerate rapid and sustainable access to cabotegravir LA for PrEP in low- and middle-income countries. Until a generic version is available, ViiV Healthcare is committed to continuing to work with partners to widen access and supply cabotegravir LA for PrEP at a non-profit price in low-income, least developed and all sub-Saharan African countries.

Mitchell Warren, Executive Director of AVAC, said: "Cabotegravir LA for PrEP is a proven HIV prevention method that must be widely accessible to people who need and want to use it, and the signing of these sublicence agreements is an important step in the process to accelerate access and impact. Aurobindo, Cipla and Viatris – through their respective sublicence agreement with MPP – will need to work closely with the Coalition to support access to this long-acting medicine in the years to come, and, hopefully, build a platform for future long-acting options as well."

Dr Philippe Duneton, Executive Director of Unitaid, said: "We are delighted that these generic manufacturers, through the selection process conducted by MPP, were able to demonstrate their capability to produce generic cabotegravir LA for PrEP and sign the first MPP agreements for a long-acting medicine. Unitaid is working with implementing partners to ensure optimal use as part of a PrEP package that enables choice, and with the Coalition and other international partners to make long-acting PrEP options equitably accessible as quickly as possible."

Cabotegravir LA for PrEP is the first and only long-acting injectable antiretroviral (ARV) for which ViiV Healthcare has gained regulatory approval in the US, Australia, Zimbabwe, South Africa and Malawi for use in HIV prevention for at risk adults and adolescents weighing at least 35kg to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to receiving it.

Press Release

For media and investors only

ViiV Healthcare has submitted marketing applications in a number of countries including the majority of countries where clinical trials were conducted, with further registrations planned.

Access the sublicence agreements

###

About cabotegravir extended-release injectable suspension

Cabotegravir LA for HIV prevention is the first and only long-acting injectable PrEP option proven superior to daily oral FTC/TDF in reducing HIV acquisition.

Cabotegravir LA for PrEP is an integrase strand transfer inhibitor (INSTI). INSTIs, like cabotegravir extended-release injectable suspension, inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease.

Cabotegravir LA for PrEP is provided as an injection administered six times per year and is initiated with a single 600 mg (3-ml) injection given one month apart for two consecutive months. After the second initiation injection, the recommended continuation injection dose is a single 600 mg (3-ml) injection given every two months. Cabotegravir oral tablets may be administered for approximately one month before initiating the first injection to assess the tolerability of the medicine.

Please see full US Prescribing Information for *Apretude*.

About the Medicines Patent Pool

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups, and other stakeholders, to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with 18 patent holders for 13 HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, a cancer treatment, four long-acting technologies, three oral antiviral treatments for COVID-19 and 12 COVID-19 technologies. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC). MPP's activities in COVID-19 are undertaken with the financial support of the Japanese Government, the French Ministry for Europe and Foreign Affairs, the German Agency for International Cooperation and SDC. More information at https://medicinespatentpool.org and follow us on Twitter, LinkedIn and YouTube.

Press Release

For media and investors only

About ViiV Healthcare

ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of acquiring HIV. Shionogi became a ViiV shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV.

For more information on the company, its management, portfolio, pipeline, and commitment, please visit www.viivhealthcare.com.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company.

MPP Enquiries:	Sophie Thievenaz	+41 79 870 85 52	(Geneva)
	press@medicinespatentpool.org		
ViiV Healthcare enquiries:			
Media enquiries:	Rachel Jaikaran	+44 (0) 78 2352 3755	(London)
	Melinda Stubbee	+1 919 491 0831	(North Carolina)
	Audrey Abernathy	+1 919 605 4521	(North Carolina)
GSK enquiries:			
Media enquiries:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Dan Smith	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Nick Stone	+44 (0) 7717 618834	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Josh Williams	+44 (0) 7385 415719	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

Press Release

For media and investors only

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, GSK's Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

Registered in England & Wales:

GSK plc
No. 3888792

ViiV Healthcare Limited
No. 06876960

Registered Office:

980 Great West Road
Brentford, Middlesex
TW8 9GS

References

[1] UNAIDS. Global HIV & AIDS statistics — Fact sheet. Available at: https://www.unaids.org/en/resources/fact-sheet Last accessed March 2023.
[2] UNAIDS. Fact sheet 2022. Available at: https://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf Last accessed March 2023.
[3] US Food & Drug Administration. FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention Last accessed March 2023.
[4] The World Bank. Country classification. Available at: https://data.worldbank.org/country Last accessed March 2023.
[5] United Nations. LDCs at a Glance. Available at: https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html Last accessed March 2023.